EXHIBIT A

AVANIR pharmaceuticals

May 16, 2014

VIA ELECTRONIC MAIL

Orange Book Staff
Office of Generic Drugs OGD/HFD-610
Food and Drug Administration
Metro Park North II
7620 Standish Place
Rockville, MD 20855

Billy Dunn, M.D., Acting Director
Division of Neurology Products
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 21-879; Nuedexta (dextromethorphan hydrobromide/quinidine sulfate) Capsules, 20mg/10mg
SN 0083; General Correspondence: U.S. Patent No. RE38,115 request to be delisted

Dear Sir or Madam:

We write to request that U.S. Patent No. RE38,115 be delisted from the FDA publication, "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the Orange Book, for NDA No. 21-879. Should you require any further information, please feel free to contact me at the below-listed number.

This submission is provided in eCTD format via the Electronic Submission Gateway. All files were checked and verified to be free of viruses using McAfee Agent, the virus signature database and virus definition files are updated on a daily basis.
Should you have any questions or require additional information regarding this submission, please contact the undersigned at (949) 389-6748.

Sincerely,

Arthur Rosenthal
Senior Director Regulatory Affairs & Quality

www.avanir.com 949.389.6700 fax: 643.6800 20 Enterprise Suite 200 Aliso Viejo, CA 92656

EXHIBIT B

FDA Home[3] Drug Databases[4] Orange Book[5]

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Patent and Exclusivity Search Results from query on Appl No 021879 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021879	001	7659282	Aug 13, 2026			U - 1093	
N021879	001	8227484	Jul 17, 2023			U - 1093	
N021879	001	RE38115	Jan 26, 2016		Y		Y

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N021879	001	NC	Oct 29, 2013

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

View a list of all patent use codes
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Return to Electronic Orange Book Home Page[6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through May 2014
Patent and Generic Drug Product Data Last Updated May 19, 2014

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

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